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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,277	08/20/2001	Peter Jozef Lco Hespel	702-010802	6608

7590 04/23/2002
Russell D Orkin
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/23/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,277

Applicant(s)

HESPEL, PETER JOZEF LEO

Examiner

Sharmila S. Gollamudi

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Claims 9-18 are included in the prosecution of this application.

Preliminary Amendment A entered on August 20, 2001 is acknowledged.

The references cited in the Search Report have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of muscle disuse syndrome, does not reasonably provide enablement for prevention of muscle disuse syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

These include: nature of the invention, breadth of the claims, state of the art, guidance

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of the specification, predictability of the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: The rejected claim is drawn to the method of preventing or treating muscle disuse syndrome in a subject with the administration of the instant compound. The nature of the invention encompasses anticipating the onset of the syndrome and subsequently administering instant composition such that the subject does not manifest any symptoms of muscle disuse.

Breadth of Claims: The complex nature of the claims is greatly exacerbated by the breadth of the claims. The claim encompasses prevention of a syndrome that has many potential causes such as aging, disease, physical handicaps, etc. In order to prevent muscle disuse syndrome completely, one would have to anticipate and envision every possible cause for the syndrome. This may or may not be addressed by the administration of the composition.

Guidance of the Specification: The guidance provided by the specification is geared towards treating at risk patients or those suffering from the symptoms. Therefore in order to diagnose the syndrome, a patient must show signs of the symptom, thus the syndrome is not prevented but rather would be treated by the administration of the composition.

The Amount of Experimentation Necessary: In order to practice the claimed invention, one of ordinary skill in the art would have to first to anticipate the onset of muscle disuse syndrome, the cause of the syndrome, the effective dosage, duration of

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treatment, etc., to determine whether or not the instant composition prevents the disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art, one of ordinary skill in the art would have to either envision a modification of the variable factors or envision an entirely new combination of the factors, and test the invention again. If unsuccessful again, the whole process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

For these reasons the claim is rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11 and 13-14, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08224073.

JP teaches a creatine (1-3g) drink for muscle fatigue or as a nutrition drink. The reference does not teach any addition exercising to increase muscle capacity. (Note abstract)

Claims 9-11, 13-14, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by XP-00210314.

XP teaches an oral creatine supplement for alleviating muscle weakness and degeneration caused by diseases (Note abstract and pg. 334, first paragraph).

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Claims 9-11, 13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0222257.

EP teaches a phosphocreatine composition for treating muscular atrophy and dystrophy (col. 1, lines 4-7). The formulation contains 1g of phosphocreatine (Note example 3).

Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Almada et al (5627172).

Almada et al teach an oral composition containing at least one creatine derivative (Note abstract). The reference discloses prior art in which creatine or its derivatives are used to treat muscular dystrophy. The creatine derivatives are administered in an amount of 1 to 30 grams a day (col. 3, lines 58-59). Further, the creatine or its derivatives can be administered in tablets, powders or candy bars (col. 4, lines 1-7 and lines 35-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almada et al (5627172).

Almada et al teach an oral composition containing at least one creatine derivative (Note abstract and col.2, lines 15-19). The reference discloses prior art in which

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creatine or its derivatives are used to treat muscular dystrophy. The creatine derivatives are administered in an amount of 1 to 30 grams a day (col. 3, lines 58-59). Further, the creatine or its derivatives can be administered in tablets, powders or candy bars (col. 4, lines 1-7 and lines 35-40).

Almada et al do not provide a specific example treating the instant syndrome or an example in which more than one creatine compound is used in food.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use more than one creatine compound as suggested by the reference. One would be motivated to do so with the expectation of at least an additive effect. Further, it is deemed obvious to use Almada's composition to treat muscle disuse since Almada teaches prior art in which creatine is used to treat this muscular disorders.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

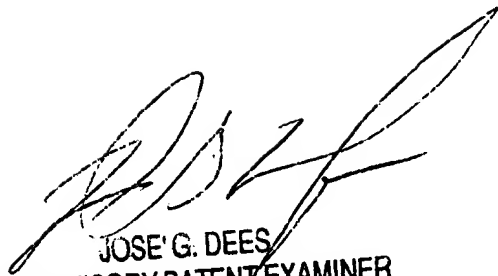
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

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April 17, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616